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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,765	04/20/2004	James Fink	016770-007100US	5232

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

MAIL DATE	DELIVERY MODE
11/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,765	FINK ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

No amendment to claims is made in response to the office action mailed on 8/2/07. Claims 1-19 are previously cancelled. Currently, claims 20-30 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **10/18/07** has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird US 6,581,600 B2.

As to claim 20, Bird in figure 1 discloses a pressure assisted breathing system having a pressure generating circuit (circuit comprising ventilators 12 and 21, and tubes 78, 88, and 117) and a respiratory circuit (circuit comprising a nebulizer 56 and tube 123 conveying nebulizing fluid). Bird further discloses control knobs 34 and 36, which can be adjusted to control a gas flow though the pressure generating circuit (col.7, lines 65-68, col.8, and lines 1-18), thus, knobs can be adjusted to provide a first gas flow of sufficiently high volume to maintain continuous positive pressure (CPAP) in the system. In col.7, lines 47-54 Bird also teaches that his system is capable of maintaining a CPAP. Figure 1 of Bird shows that the respiratory circuit is separate from a high flow gas line and no additional pressure is maintained at this gas line, thus a second gas flow though tube 123 is inherently lower volume than the first flow. Bird further discloses a patient interface (11/endotracheal tube, see col.4, line 31) being engaged with the patient's respiratory system. Figure 1 of Bird shows a nebulizer (52) is connected to the second gas flow of lower volume, thus, dilution of the aerosolized medicament delivered to the patient's respiratory system is inherently prevented. Although Bird lacks detailed method step as cited in claim 20, however, it would have been obvious to one of ordinary skill in the art to perform the method of respiratory therapy as claimed while using the pressure assisting breathing system of Bird.

As to claims 29 and 30, Bird discloses said interface is an endotracheal tube (see col.4, lines 31).

Claims 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird US 6,581,600 B2 in view of Davison GB 2,272,389.

As to claim 21, Bird lacks a vibrating aperture-type aerosol generator for aerosolizing the liquid medicament and a connector for connecting the nebulizer to the respiratory circuit so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. However, Davison teaches a vibrating aperture-type aerosol generator (fig.2) for aerosolizing the liquid medicament and a connector (2) for connecting the nebulizer to the respiratory circuit (32) so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13).

As to claim 22, Davison teaches the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13).

As to claim 23, Davison discloses a reservoir (14) having a variable capacity (fig.2); consequently, it would have been obvious to adjust the volume of the reservoir to any desired volume including 4ml or less.

As to claim 24, Bird discloses a CPAP system, a pressure-generating circuit with a first gas flow of sufficiently high volume to maintain continuous positive airway pressure in the

system, a respiratory circuit connected to the pressure generating circuit to a patient interface device as applied for claim 20. Bird teaches a nebulizer (56), which can be adapted to introduce a liquid surfactant. Bird however lacks a vibrating aperture type nebulizer coupled to the respiratory circuit. However, Davison teaches a vibrating aperture-type aerosol generator (fig.2) for aerosolizing the liquid medicament and a connector (2) for connecting the nebulizer to the respiratory circuit (32) so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13). Riggs discloses whereby the patient breathes the aerosolized surfactant through the patient interface device (col.14, lines 20-38). Although Bird lacks detailed method step as cited in claim 24, however, it would have been obvious to one of ordinary skill in the art to perform the method of respiratory therapy as claimed while using the pressure assisting breathing system of Bird as modified by Davison.

As to claim 25, Bird lacks the surfactant is phospholipids. However, it is known in the art that the surfactant can have variety of composition including phospholipids. Furthermore, it would have been obvious to select a particular composition of surfactant to meet patient's therapy requirement.

As to claims 26 and 28, Bird lacks wherein 6-18% of the aerosolized surfactant is delivered to the patient and wherein the dose is equal to 10 mg or less of surfactant. However, the particular amount of each dose and the particular amount of aerosolized medicament that is delivered to a patient can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular amount including 6-18% and 10mg or less.

Furthermore, the particular amount and concentration of medicament is dependent upon the particular medical needs of a patient and is adjusted accordingly.

As to claim 27, Bird lacks the entire dose is delivered to the patient and the dose is equal to 10 mg or less of surfactant. However, Davison teaches the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bird in order to provide the dosing capacity as claimed for the purposes of delivering contents of medicament without the need to replenish the reservoir as taught by Davison.

Response to Arguments

Applicant's arguments with respect to claims 20-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Strickland (5,246,012) pertains to an interface apparatus with a pressure generating circuit and a respiratory circuit.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/20/2007

Shumaya B. Ali
Examiner
Art Unit 3771

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11/23/07